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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/706,309	11/12/2003	Daniel D. Bartnick	081583-0291	5759	
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FOLEY & LARDNER LLP 150 EAST GILMAN STREET			HENDRICKS, KEITH D		
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MADISON, W	MADISON, WI 53701-1497			1761	
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
×.	10/706,309	BARTNICK ET AL.				
Office Action Summary	Examiner	Art Unit				
	Keith Hendricks	1761				
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on						
2a) This action is <b>FINAL</b> . 2b) ☑ This	This action is <b>FINAL</b> . 2b) This action is non-final.					
3) Since this application is in condition for allowar	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-18</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-18</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers						
9) The specification is objected to by the Examine	r.					
10) The drawing(s) filed on is/are: a) acce		Examiner.				
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correct	•					
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	)-(d) or (f).				
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents						
3. Copies of the certified copies of the prior	·	ed in this National Stage				
application from the International Bureau		ad.				
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)	Λ □ Interchange 0	(DTO 442)				
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)	4)  Interview Summary Paper No(s)/Mail Da	ate				
3) X Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) Notice of Informal F	Patent Application (PTO-152)				
Paper No(s)/Mail Date <u>4/04; 3/05; 2/06</u> .	0) [					

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#### **DETAILED ACTION**

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the production of a natural vanilla extract, does not reasonably provide enablement for the production of any random type of extract from any random "solid botanical material". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Paragraph 0009, at page 4 of the specification, states:

The present methods may be used to produce natural flavor extracts from a variety of botanical materials. While the present methods are illustrated herein by reference to descriptions of the production of natural vanilla extracts, the methods can also be used to produce extracts of other botanical materials such as cocoa beans, tea leaves, coffee beans and carob beans.

However, the specification does not provide sufficient guidance toward the selection of appropriate and effective alternative starting botanical materials. The specification does not state which parts of other plants may be utilized, for example from the roots, stems, leaves, flowers, fruits, or seeds/pods/beans. The instant specification demonstrates the use of vanilla beans alone. The instantly-claimed method utilizes an aqueous alcohol solvent, yet the specification fails to disclose which types of plant materials may be utilized in the claimed process, such that a functional extract results. Only certain substances within plants would be expected to be soluble in an aqueous alcohol solution, yet the instant specification does not provide sufficient guidance regarding the appropriate and necessary selection of plant materials and protocol, beyond those of the exemplified vanilla bean extract. Finally, the specification does not provide a sufficient description of the desired resultant "primary extract", i.e. a flavor, odor, colorant, pharmaceutical compound, etc. beyond those of the exemplified vanilla bean extract, such that the skilled artisan would have a base level of knowledge of that which is to be produced by the present method (and that which is part of the instant product claims, as well).

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## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-6 and 17-18 are rejected under 35 U.S.C. 102(a) as being anticipated by the Biocatalysts Technical Bulletin Number 110 (of record; also cited and referenced in parent application 10/706,309).

NOTE: The Biocatalysts Technical Bulletin number 110 does not provide a publication date within its text. However, a search of the website from which it was derived (<a href="www.biocatalysts.com">www.biocatalysts.com</a>), along with an internet archive search of the corresponding Technical Bulletin web pages, reveals that this bulletin was first posted on the website as of March 07, 2003, and was posted in ".pdf" format on the website as of April 09, 2003. Thus, the reference is applicable prior art, as it "was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent" (35 U.S.C. 102(a)). It is further noted that such web pages and ".pdf" files are considered to be "printed publications" and within the public realm.

The Biocatalysts Technical Bulletin number 110 discloses the use of a mixed enzyme composition which is "high in glucosidase activity, which has been specially developed to aid the extraction of natural vanilla extracts from vanilla pods" (pg. 2, col. 2). The vanilla beans are chopped, and dispersed in water, which may also contain up to 25% aqueous alcohol. The mixture has a pH of from 4.0 to 5.5, and a controlled temperature in the range of 40-60°C (104 – 140 °F). The beans and aqueous solvent are incubated with the enzyme mixture, with agitation, for between 3-16 hours. Upon completion of the enzymatic digestion, "the pH is adjusted to 7.0 – 7.5 and alcohol is added to a final concentration of at least 70%. Vanillin and other flavor compounds are solubilized by the alcohol, and the flavors can then be extracted. Column 4 of page 1 discloses that ethanol is used for the aqueous alcohol solution. Although not explicitly stated, the enzyme mixture known as Depol<sup>TM</sup> 40L contains cellulase, hemicellulase, xylanase and pectinase activity (see columns 1-2, page 2). The description of single-, double- and triple-fold vanilla extracts is provided at columns 3-4 of page 1, where a single-fold extract is produced by 13.5 ounces per gallon of solvent, and double-fold extracts are extracted from 26.7 ounces of vanilla pods per gallon.

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Thus the claimed invention is anticipated by the reference. Claims 3-4 are directed to a product produced by the recited process. A recitation of the intended process of making of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art composition possesses the same tangible, material and discernible properties of the claimed product, regardless of the method by which it is made, then it meets the claim. Further, it is noted that claims 5-6 and 17-18, generally directed to "a food product", an "oral care product" and "a pharmaceutical product" do not provide sufficient specificity of the claimed products to distinguish them from the natural extract compositions of claims 3-4, and thus are included in this rejection.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Biocatalysts Technical Bulletin Number 110, in view of Kalenian et al. (US PAT 6,203,837).

The Biocatalysts Technical Bulletin number 110 is taken as cited above.

Kalenian et al. discloses a method for producing large quantities of extracts from solid raw plant materials, by utilizing pressure treatment with pressurized solvent. Column 6, lines 60-65 states that, while coffee beans are exemplified, this process may be used with a number of solid raw materials, such as tea leaves, cocoa, and vanilla beans. The system utilizes non-flow conditions which enable the addition of aqueous solvent, as well as providing an outlet valve for the removal and collection of the aqueous flavor extract. The conditions of the pressure treating step are generally outlined at columns 10-11, and depend upon the condition of the solid materials, whether they are in whole bean form or ground. Pressures range from 50 psi to 150 or even 1000 psi. Typical pressure treatment times is about 10 minutes (col. 11). Additional aqueous solvent may be added "to yield a desired level of extraction and final extract concentration" (col. 11, lines 24-26). The example states that the hot water used is at a temperature of 193°F and the pressure is 90 psig. The reference states that, "for example, concentrated

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coffee extracts produced according to some embodiments of the invention can be used for producing coffee syrups, coffee ice creams, iced coffee beverages, coffee perfume, etc., all of which can display excellent flavor, sweetness, and/or fragrance and maintain the varietal characteristics of the coffee from which the products were produced. The current invention also provides methods and apparatus that are flexible enough to allow for production of a wide variety of extracts having different concentrations and degrees of extraction to suit a variety of purposes and applications." Kalenian et al. does not teach the use of a glycosidase-type enzyme with the extraction method.

It would have been obvious to one of ordinary skill in the art to have utilized the system and apparatus provided by Kalenian et al., for the production of a vanilla extract as disclosed by the Biocatalysts Tech. Bulletin. The crux of the instantly-claimed inventive contribution appears to be the use of the "enzyme material having glycosidase activity" in producing a vanilla extract, either under pressure or at ambient pressures, within well-known system methods. The Bulletin provides for the use of the "enzyme material having glycosidase activity" in producing a vanilla extract, and provides the general protocol and parameters for producing a vanilla extract. As the teachings of the Bulletin do not specifically provide an apparatus for carrying out the procedure described therein, the ordinarily-skilled artisan would have necessarily referred to teachings of known systems in the art, such as that of Kalenian et al. Kalenian et al. specifically states that the protocol and apparatus disclosed therein may be used with vanilla beans to produce the desired flavor extract, and thus it would not have involved an inventive step for one of ordinary skill in the art to have utilized this system for the production of a natural vanilla extract with an enzyme material having glycosidase activity, as instantly claimed.

Regarding the specifically-recited food and health care products of instant claims 3-18, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added the resultant vanilla extract to a variety of orally-consumed products in order to take advantage of the flavor and other sensory properties imparted by the vanilla extract. Such uses for vanilla extracts were notoriously well-known and practiced in the art at the time the invention was made. Kalenian et al. discloses that the extracts made therein, exemplified by coffee, "can be used for producing coffee syrups, coffee ice creams, iced coffee beverages, coffee perfume, etc., all of which can display excellent flavor, sweetness, and/or fragrance," and thus the same could easily be followed for vanilla extract.

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#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KEITH HENDRICKS PRIMARY EXAMINER